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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,593	06/21/2001	Daniel E. Afar	G&C 129.18USD1	9040

36327 7590 08/24/2004

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EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/887,593	<b>Applicant(s)</b> AFAR ET AL.	
	<b>Examiner</b> Gary B. Nickol Ph.D.	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 72,80 and 90-105 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 72,80 and 90-105 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                        |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

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Re: Afar *et al.*

Date of priority: 08/10/1998

***Response to Amendment***

The Amendment filed 06/21/2004 in response to the previous notice of non-responsiveness (06/08/04) is acknowledged and has been entered.

Upon review and reconsideration, Groups I, II, VI, and VII (from the restriction requirement mailed 05/15/2003) are rejoined.

72, 80, 90-105 are currently under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

**Rejections Maintained:**

Claims 72, 80, 90-91 **remain** rejected and new claims 92-105 are rejected under 35 USC 112, 1<sup>st</sup> paragraph, as failing to comply with the enablement paragraph for the reasons of record in the Action mailed 10/20/03 (pages 5-8) and for the reasons set forth below.

Applicants have argued (Remarks, 03/12/04) that the pending claims recite methods for inhibiting 19P1E8 activity, and that the present specification provides a number of tools with which a skilled artisan can readily inhibit 19P1E8 activity. Such tools include antibodies that

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bind to 19P1E8 as well as compositions that inhibit 19P1E8 transcription and translation.

Applicants further argue that one of ordinary skill in the art would not need to engage in undue experimentation to practice the claimed invention in light of these teachings. This argument has been considered but is not found persuasive for the reasons of record. Further, these arguments are general in nature and are directed solely to the opposite position in the absence of any supporting evidence. As set forth previously, applicants are not enabled for using any and all compositions capable of inhibiting the 19P1E8 protein. Further, as the claims broadly encompass method of treating cancer, the state of the art of the art with regards to such treatment is highly unpredictable. Garattini S. (Annals of Oncology, Vol. 14, pages 813-816, 2003) teaches that even the latest drugs on the market do not achieve the desired improvement considering the expectations generated by the advances in fundamental knowledge of cancer cell proliferation and dissemination. Further, new approaches for treating cancer, including those that administer monoclonal antibodies need further evaluation with increases in tumor cell resistance and toxicities (1<sup>st</sup> column).

Thus, for the reasons of record and for the reasons set forth above, applicant's arguments have not been found persuasive and the rejection is maintained.

No claim is allowed.

**All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.**

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.  
Primary Examiner  
Art Unit 1642

**GARY NICKOL**  
**PRIMARY EXAMINER**

GBN

A handwritten signature in cursive script that reads "Gary B. Nickol".